## American Heart Association Redefining Women's Health: From Heart to Head to Hormones

**Key Dates** 

RFP posted: October 31, 2025
ProposalCentral open: November 4, 2025

Pre-proposal deadline: Tuesday, January 6, 2026

Invitation to submit full proposal: Mid-February

Invited full proposal deadline: Tuesday, April 14, 2026

Peer Review April – May 2026

Award notification: June 2026 Award start: July 1, 2026

### Important Notes:

- Proposals must be received no later than 3 p.m. Central Time on the deadline date. Early submission is encouraged. The American Heart Association does not accept late proposal submissions, grant extension requests, or have an appeals process.
- Before beginning an application, see the <u>AHA Application Resources</u> page for requirements that apply to all AHA research awards. Also view AHA's research Policies and Statements.
- Proposals must be <u>submitted electronically via Proposal Central</u>. The system will open eight weeks prior to the application deadline to complete the proposal and upload required documents. Applicant can create required documents in advance; refer to the <u>AHA Application Instructions (PDF)</u>. All submissions require the signature of a designated institutional representative.
- Applicants must be <u>AHA Professional Members</u> at the time of proposal submission. <u>Join or renew</u> when preparing an application in Proposal Central, or by phone at <u>+1-888-242-2453</u> or <u>972-349-5803</u>. Membership processing may take 3-5 days; do not wait until the application deadline to renew or join. The AHA expects all mentors associated with training/mentored research awards to maintain active AHA membership, as well.

# Summary

Studio Red/Go Red for Women Fund/AHA invites researchers, clinicians, entrepreneurs, and innovators to submit pre-proposals for funding consideration to advance groundbreaking research and novel solutions in

women's health. Selected pre-proposals will be invited to submit full proposals for competitive grants that aim to close critical knowledge and care gaps. A total of \$1 million is available to fund up to 10 investigators / investigative teams proposing innovative technologies that disproportionally or exclusively impact women's health.

During the 1-year award period, Studio Red will provide support and educational content on IP, regulatory strategy, reimbursement and commercialization strategies, fundraising and pitch development etc. to grantees via monthly webinar sessions for the duration of the grant period.

At the conclusion of the award period, 1-2 awardees may be selected for advancement in Studio Red. Studio teams would support the top 1-2 grantees and incubate the early company formation process helping the team reach key funding milestones. Upon successful completion of the Studio Red incubation process, the goal would be to have at least one of these companies created and ready for follow on funding and external launch.

### Purpose/Background

Despite significant progress in biomedical research, many conditions that disproportionately, differently, or distinctly impact women remain underdiagnosed, undertreated, and underfunded. This call focuses on four priority areas where transformative science and innovation are urgently needed:

Conditions that disproportionally impact women or present differently in women, but treat both men and women:

- Ischemia with Non-Obstructive Coronary Arteries (INOCA) and Cardiovascular Microvascular Disease (CMD)
- Autoimmune Disease Screening, Predictors, and Care Models

Conditions that distinctly impact women:

- Next-Generation Treatments for Endometriosis
- Classification and Care Models for Heavy Menstrual Bleeding (HMB)

Priority Topic Areas/Research Areas of Interest

Conditions that Disproportionately or Differently Impact Women

Ischemia with Non-Obstructive Coronary Arteries (INOCA) or CMD

Autoimmune Disease: Screening, Predictors, and Care Models

- Market & Burden: Approximately 80% of autoimmune diseases occur in women, with conditions such as lupus, rheumatoid arthritis, and multiple sclerosis accounting for over \$100 billion in annual U.S. healthcare costs.
- Clinical Considerations: Diagnosis is often delayed by years due to nonspecific symptoms and lack of predictive screening tools. Fragmented care models lead to inconsistent disease management and poorer outcomes for women.
- Research Gaps: Early biomarkers, risk stratification tools, and multidisciplinary care models tailored to women are urgently needed to reduce disease burden and improve quality of life.

## Conditions that Exclusively Impact Women

Endometriosis: Novel Therapies Beyond Hormonal Suppression

- Market & Burden: Affecting an estimated 10% of reproductive-age women globally (~190 million), endometriosis leads to chronic pelvic pain, infertility, and an estimated \$22 billion annual economic burden in the U.S. due to lost productivity and medical costs.
- Clinical Considerations: Current treatments rely heavily on hormonal suppression or surgical intervention, both of which can limit fertility and have high recurrence rates.
- Research Gaps: Non-hormonal therapies, early detection biomarkers, and disease-modifying strategies are critically needed. Innovations in immunology, neuroinflammation, and regenerative medicine may yield breakthrough treatments.

Heavy Menstrual Bleeding (HMB): Classification to Guide Care

- Market & Burden: HMB affects up to one in four women of reproductive age and is a leading cause of iron-deficiency anemia worldwide. Direct medical costs and lost productivity exceed \$12 billion annually in the U.S.
- Clinical Considerations: Existing classification systems (e.g., PALM-COEIN)
  are inconsistently applied and often fail to capture symptom burden or
  guide personalized therapy.
- Research Gaps: Improved phenotyping, validated patient-reported outcome measures, and evidence-based algorithms to match classification with effective interventions remain unmet needs.

### Translational potential:

Only proposals with a feasible path for implementation, scalability and potential commercialization will be considered. Awards will be made only to eligible nonprofit institutions described in the Relevant Policies and

Requirements section below. However, inclusion of subcontracted industry partners who have expertise in key areas of the proposed studies is encouraged.

### Governance/Oversight:

Studio Red will provide support and educational content on IP, regulatory strategy, reimbursement and commercialization strategies, fundraising and pitch development etc. to grantees via monthly webinar sessions for the duration of the grant period.

### Timelines and Milestones:

Grantees will present their work at a virtual midpoint presentation to key stakeholders from AHA, including Studio Red, GRFW Fund, and AHA broadly. Feedback, including additional recommendations and programming to support the remainder of the grant period, and final presentation selection criteria will be provided at this meeting.

Final presentations will be held at the end of the award period where 1-2 ideas may be selected for Studio Red incubation.

## Eligibility

- Academic investigators, clinical researchers, academic researchers or investigators associated with startup companies, and non-profit innovators are eligible. Only eligible non-profit institutions may create and submit a proposal.
- Collaborative proposals spanning disciplines (e.g., cardiology + data science, gynecology + bioengineering) are welcome.
- Applicant must be an <u>AHA Professional Member</u> at the time of preproposal submission.
- AHA research awards are limited to U.S.-based non-profit institutions, including medical, osteopathic, and dental schools, veterinary schools, schools of public health, pharmacy schools, nursing schools, universities and colleges, public and voluntary hospitals and others that can demonstrate the ability to conduct the proposed research.
- Applicant must have one of the following designations at the time of proposal submission – not award start date, depending on career stage and each individual's situation. An awardee must maintain one of the designations listed below throughout the duration of the award. Please consult with your institution's grant officer.
  - o U.S. citizen

- Permanent resident
- Pending permanent resident (must have filed Form I-485 for permanent resident status and obtained an I-797C Notice of Action that the application has been received by USCIS and case is pending)
- E-3 Visa specialty occupation worker
- o F-1 Visa student (for predoctoral and postdoctoral fellows only)
- G-4 Visa family member of an international organization employee
- o H1-B Visa temporary worker in a specialty occupation
- J-1 Visa exchange visitor (pre- and postdoctoral fellowships only; all other awardees must obtain an H-1B or equivalent by the proposal due date)
- O-1 Visa temporary worker with extraordinary abilities in the sciences
- o TN Visa NAFTA Professional
- DACA Deferred Action for Childhood Arrivals

#### At the time of award activation:

- This program places no limit on eligibility based on career stage, academic rank or discipline. It requires only evidence of employment at a qualified institution.
- While no minimum percent effort is specified, the principal investigator must demonstrate that adequate time will be devoted to ensuring successful completion of the proposed project
- Proposed projects may include—but are not limited to—basic, translational, or clinical research; digital health tools; novel therapeutics; diagnostic development; predictive analytics; and innovative care delivery models. Cross-disciplinary collaborations and communityengaged approaches are strongly encouraged.

#### **AWARD DETAILS**

Award Duration: 1 year

Number of Awards: The American Heart Association anticipates awarding up to 10 awards.

Awardees will be selected based on scientific merit and how each investigator aligns with the Association's mission to be a relentless force for a world of longer, healthier lives.

Award Amount: The maximum budget amount a research team may request is \$100,000 USD.

The Heart Association reserves the right to determine the final award amount for competitive projects based on need and potential impact.

Budget: \$100,000 per year, including 10 percent indirect costs

The award may be used for salary and fringe benefits of the principal investigator, collaborating investigator(s), and other participants with faculty appointments, and for project-related expenses, such as salaries of technical personnel essential to the conduct of the project, supplies, equipment, computers/electronics, travel (including international travel), volunteer subject costs, data management, and publication costs, etc. The proposed budget must be justified in the application.

AHA does not require use of the NIH salary cap.

Total Award Amount: \$100,000 per selected project

# Required Pre-Proposal

All pre-proposals will be submitted via <u>ProposalCentral</u> and require the following three documents:

1. Research Proposal – up to 3 pages, inclusive of all sections noted below. Please address all of the following points:

#### A. Concept:

- Clearly and explicitly articulate the project's innovation and the potential impact on women's health.
- Provide a solid rationale for the work.
- Discuss new avenues of investigation that will be revealed, if successful.
- Innovation Novelty of the proposed approach or technology.
- Impact Anticipated outcomes and potential to reduce disparities in women's health.

- B. Research Plan: Describe specific studies you will conduct in addressing the seminal question(s) you propose to pursue. Presentation of studies as a set of Specific Aims is acceptable but not required. Include:
  - A description of the technological approaches you plan to utilize and/or develop in the pursuit of your studies.
  - A description of the required datasets, images, health and other records, etc. that will be required to conduct your proposed studies, as well as your access to these resources.
    - For studies involving human subjects/human subject records, projects must include study participants/records who are underrepresented and/or underserved with regard to healthcare delivery. The proportion of these individuals/records in proposed studies should be reflective, at a minimum, of their representation in the population in which these individuals/records exist.
  - An anticipated timeline for achieving key milestones over the course of this three-year study.
  - An estimated total budget requirement and brief rationale, including the proposed number of paid staff and the approximate allocation (if applicable) between the institutions within the team.
  - [Optional] Video provide α link to α 2-minute video briefly describing your background and research area
- C. Team: Describe the research team key personnel and why they have been sought out for these studies. Include:
  - The team's experience with and/or capacity to develop new tools and methods that support creative approaches to the questions under study.
  - The lead applicant/institution's capacity to receive and manage research awards of the scale available.
- D. Ethical, Legal and Social Implications: Describe the ethical, legal and social implications that are likely to be pertinent for your proposed studies and how you will positively address them.

- E. Development/commercialization Plan: Should your studies be successful, describe the opportunity for their development and potential commercialization. A full business plan is not required. However, applicants should address the following:
  - What is the market opportunity for the anticipated product/technology/service that could result from your research and what is a reasonable timeline for development and commercialization?
  - Following conclusion of the studies as proposed, what additional resources – financial, business development expertise, etc. – might be needed, and what are possible opportunities/venues for identifying and securing these resources?
- 2. <u>Biosketch</u> (Principal Investigator only, NIH format, max. 5 pages)

AHA biosketch requirement: All applicants (excluding fellows) are to explicitly state in the Personal Statement section of their biographical sketch how they contribute to a safe and inclusive work environment. In addition, mentors on Fellowships, Career Development Awards, and Diversity Supplements should complete recognized training specific to sexual and gender-based harassment.

3. Literature Cited (two-page limit)

NO OTHER UPLOADS ARE PERMITTED at the Pre-Proposal stage.

#### HOW TO SUBMIT YOUR PRE-PROPOSAL

- Log on to <u>ProposalCentral</u> and navigate as follows:
   Create New Proposal > Filter by Grant Maker
   Select "American Heart Association"
   Locate "Redefining Women's Health: From Heart to Head to Hormones" and click "Apply Now"
- Title
   Enter Title
- Accept Program Requirements
   In this section, you will acknowledge you have read and understand all program requirements for the Innovative Project Award.

- Applicant/PI and PI Demographics
   In this section of the application, you will provide information about yourself, your academic career, effort and professional time, demographics, citizenship, location of work for the research project and college degrees.

   Save each section as you complete it.
- Institution and Personnel In this section, you will provide information about your institution including identifying the Grants Officer, Fiscal Officer, and Technology Officer.

These Officers must be selected from the list of registered users. Contact your institution's grants office if you are unsure of which person to select from the list. It is important to select the correct Grants Officer, as he or she is responsible for the final submission of your LOI to the AHA.

- Third Party Personnel -- Please provide the contact information (full name and email) for all consultants or collaborators (if applicable); only include this information in this specific ProposalCentral field. It should not be included in the one-page pre-proposal upload, project summary, or nonscientist summary.
- Project Summary & Non-Scientist Summaries, Classifications
  - Prepare your Non-Scientist Summary Enter a description of your project that is written to be understood by non-scientists. This information may be reviewed by people who do not have scientific or medical backgrounds. Please be clear and avoid technical and scientific terms, when possible. When formulating your lay summary, it might help to imagine that you are explaining your work to a new acquaintance who does not work in the science field.

NOTE: It is incumbent upon the applicant to make a clear link between the project and the mission of the AHA. The lay summary will be assessed in terms of potential impact on the AHA mission; this will be factored into the overall priority score as noted in the peer review criteria.

Complete the Project Summary
 Write a concise description or abstract describing the work proposed.
 This should be as brief as possible since you also will be required to upload a separate LOI document. Note: This field will not accept any special characters or keystrokes (e.g., β, π, etc.).

- Science Classifications and Research Classification
   These classifications are independent of each other and will not affect the peer review of your application.
  - Research Classification Type: Select the Research Type that best fits the research being conducted in your lab (basic, clinical, or population).
  - Science Classification: Choose both a Primary Classification and a Secondary Classification. Current science classifications are listed on the AHA website.
- Upload One Attachment
  - Upload your pre-proposal as a .PDF document. See Pre-proposal Guidelines below. (Limited to 3 pages).

NOTE: References are not required nor accepted at the pre-proposal stage and will be required if selected for a full proposal.

• Validate, Signature Page(s), and Submit

### Required Pre-Proposal Review

Only applicants who submit a pre-proposal will be eligible to be considered for invitation to full application.

For the required pre-proposal submission, the Association will perform an asynchronous peer review with scientific and business volunteer experts to assess the eligibility of the applicants and the relevance of their submissions to the competition's purpose, objectives, and research areas.

Pre-proposals that do not align with the competition guidelines will be withdrawn. Please note that there is no formal appeal process once decisions are made.

# Invited Full Proposal

Invited Full Application Required Documents and Peer Review Process

### Invited Full Proposal

- Research Plan (10 pages)
- Biosketch (5 pages)
- Budget Justification Form (DOCX) (2 pages)
- <u>Literature Cited</u> (4 pages)

- Vertebrate Animal Subjects, if applicable (no page limit)
- Other Third Party Personnel (if applicable)
- Collaborating Investigator's Biosketch (5 pages)
- Collaborating Investigator's Letter (5 pages)
- Consultant's Letter (5 pages)

Applicants are also required to complete the following sections in Proposal Central:

- Project Summary Write a concise description or abstract describing the work proposed. This should be as brief as possible, since you also will be required to upload a separate pre-proposal document. Note: This field will not accept any special characters or keystrokes (e.g.,  $\beta$ ,  $\pi$ , etc.).
- Non-Scientist Summary Enter a description of the project that is written to be understood by non-scientists. This information may be reviewed by people who do not have scientific or medical backgrounds. Be clear and avoid technical and scientific terms, when possible. When formulating your lay summary, it might help to imagine that you are explaining your work to a new acquaintance who does not work in the science field. NOTE: It is incumbent upon the applicant to make a clear link between the proposed project and the mission of the American Heart Association.

### FORMAT/TYPE REQUIREMENTS

You must comply exactly with the AHA's format/type requirements and page limits. Failure to comply will result in the administrative withdrawal (disqualification) of the pre-proposal.

- Documents must be single-spaced.
   No more than 15 characters per inch (cpi) or an average of no more than 15 cpi (cpi includes symbols, punctuation, and spaces).
- No less than ¾" page margins on all four sides.
- Maximum of 50 lines per page.
- Arial Font style, 12-point font size for Windows users; Helvetica Font style, 12-point font size for Macintosh users.
- Only Portable Document Format (PDF) files are accepted.

  Note: The ProposalCentral electronic system will reject a document that exceeds the page limit.

Internet website addresses (URLs) may not be used to provide information necessary to the review because reviewers are under no obligation to view the Internet sites. Moreover, AHA reviewers are cautioned not to directly access an Internet site, as it could compromise their anonymity. The only place a URL may be used is in the biographical sketch as described in the instructions for that form.

The AHA has the responsibility to make final determination of conformance to format requirements and the authority to withdraw applications. This decision is final and not subject to appeal.

#### Peer Review

Peer Review Criteria for Invited Full Proposals

Applications will undergo peer review by a grant review panel ("Review Panel"), convened and overseen by the Heart Association.

The Review Panel will include expert scientific and business reviewers in the priority topic areas. Expert reviewers may include international members as well as reviewers from the USA. Additional ad-hoc reviewers may be obtained to bring additional expertise to support the review process. The Review Panel may meet in person or virtually at the discretion of the American Heart Association. Applicants are prohibited from contacting American Heart Association peer reviewers. This is a form of scientific misconduct and will result in the removal of the application from funding consideration and institutional notification of misconduct.

Restrictions: Peer Reviewers: The American Heart Association DOES NOT permit the use of a large language model (LLM – e.g., ChatGPT) or an artificial intelligence tool to generate and/or edit content in peer review critiques. Uploading of any portion of a research proposal into a large language model (LLM – e.g., ChatGPT) or an artificial intelligence tool to assist in writing a critique of the proposal is explicitly prohibited as it is a violation of The American Heart Association's Peer Reviewer Certification Statement (to include confidentiality, non-disclosure, and conflict of interest).

The American Heart Association reserves the right to an initial triage, whereby a minimum of half of the submissions may be triaged.

Applicants should never contact reviewers regarding their applications.

Discussing the content of an application or attempting to influence review outcome will constitute a conflict of interest in the review. Reviewers must notify

the AHA if an applicant contacts them.

To judge the merit of the application, reviewers will comment on the following criteria. Fully address these in your proposal.

- 1. Innovation: Assessment of the proposal's innovative nature -- Is the proposal innovative for the investigator and not a logical next-step? Is the proposal original and have the potential to ultimately lead to critical discoveries or major advancements that will accelerate the field of women's health? For example: Does the proposal challenge existing paradigms and present an innovative hypothesis or address a critical barrier to progress in the field? Does the proposal develop or employ novel concepts, approaches, methodologies, tools, or technologies for this area?
- 2. Impact: Does the proposed research disproportionally or exclusively impact women's health? Does the proposal have a high probability of sustained and powerful influence on the research field(s) of study? How does this proposal relate to and support the mission of the American Heart Association: to be a relentless force for a world of longer, healthier lives? This potential impact assessment will be based primarily on the Summary for Non-scientists. This assessment will be factored into the Impact peer review criterion, which will account for 5-10% of the overall priority score. Does the proposed research disproportionally or exclusively impact women's health?
- 3. Significance: Does this proposal address an important problem directly related to women's health? If the aims of the application are achieved, will scientific knowledge or clinical practice be significantly impacted? Will there be an effect on the concepts, methods, and technologies that drive this field?
- 4. Approach: Are the conceptual framework, design, methods and analyses adequately developed, integrated, well-reasoned and appropriate to the aims of the proposal? Does the applicant acknowledge potential problem areas and consider alternative tactics?
- 5. Investigator: Is the principal investigator appropriately trained and suited to carry out this work, even if a new area of investigation? Does the investigative team bring complementary, appropriately qualified, and integrated expertise to the proposal (if applicable)? All applicants (excluding fellows) are to include a statement in the Personal Statement

section of their biographical sketch that explicitly states how they contribute to a safe and inclusive work environment. In addition, mentors on Fellowships, Career Development Awards, and Research Supplements should complete recognized training specific to sexual and gender-based harassment.

- 6. Environment: Does the environment in which the work will be done contribute to the probability of success? Does the proposal demonstrate that resources will be available to complete the project? Does the proposed benefit from specific unique features of the environment, or subject populations, or employ useful collaborative arrangements?
- 7. Lay Summary/Summary for Non-Scientists: How well written is the lay summary in explaining to a non-scientist audience the research proposed and importance? Does the Lay Summary adequately explain the major health problem being addressed by this study? Does it provide specific questions and how the project will address them? Does it provide information on the overall impact of this work and the potential advances in the field? Does it relay how the proposal supports the mission of the American Heart Association?
- 8. Business and Commercialization Impact: Is there a high likelihood that the research could translate into a viable company? Do product development timelines look reasonable and achievable?

# Relevant Policies and Requirements

# Intellectual Property

Any inventions, intellectual property, and patents resulting from this funding are governed by the AHA Intellectual Property Policy for Research Funding (the "IP Policy"); provided that the IP Policy is modified as follows:

- The definition of Net Income in the IP Policy is replaced in its entirety with the following language:
- "Net Income" means all Gross Income received related to commercialization of Intellectual Property resulting, in whole or in part, from an Award, less third-party, out-of-pocket expenses related directly to costs associated with application and registration required to establish ownership rights in or protection of the Intellectual Property. All other

- costs, including Unrecovered Indirect Costs and Internal Distributions, are not deductible when calculating Net Income.
- Section V, Paragraph D of the IP Policy is replaced in its entirety with the following: language
- Institution shall pay the AHA annually a percentage of the Net Income
  derived from Intellectual Property conceived or reduced to practice in the
  performance or as a result of an Award, regardless of the amount of Net
  Income actually received, equal to AHA's portion of support (expressed as
  a percentage) for the work or research giving rise to the Intellectual
  Property. In no event shall the application of the foregoing result in either
  AHA or Institution receiving less than 15% of Net Income.
- A new Section V, Paragraph F is added to the IP Policy with the following language:

Awardee shall provide AHA with an exclusive option to license any intellectual property rights and related know-how created or developed under the award (the "Exclusive Option"). If AHA decides, at its sole discretion, to exercise the Exclusive Option, AHA and Awardee will negotiate in good faith for a period of six months following the end of the Award the commercial terms of a license agreement. If the AHA and Awardee cannot come to an agreement within the six month period, negotiations will cease, and the intellectual property rights will continue to be held exclusively by Grantee, subject to the IP Policy, as modified above.